Bayer Health Care Consumer Care Division

1748 "03 APR -4 P4:29



March 12, 2003

Office of Special Nutritionals Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835 MAR 1 3 2003

Subject: 30-Day Post Market Notification for Structure/Function Claims; One-A-Day® Women's Dietary Supplement

Dear Sir or Madam:

Bayer HealthCare, Consumer Care Division submits the information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product label of One-A-Day® Women's Dietary Supplement.

Dransam Maren	One-A-Day® Women's
PRODUCT NAME	
NAME /ADDRESS OF	Bayer HealthCare
DISTRIBUTOR	Consumer Care Division
	36 Columbia Road
	P. O. Box 1910
	Morristown, New Jersey 07962-1910
NAME OF DIETARY	One-A-Day® Women's Dietary Supplement
INGREDIENT/SUPPLEMENT	Multivitamin/Multimineral Supplement
(SUBJECT OF THE	
STATEMENT)	
TEXT OF STATEMENT	
BEING MADE	
Top Panel of Carton	Supports Bone Strength with Bone Building
-	Nutrients including Calcium, Magnesium,
<u> </u>	Vitamin D and an appropriate level of
	Vitamin A*
	• Promotes a Healthy Reproductive System as
	a woman's body changes, with Folic Acid,
	Vitamins B6, B12, Magnesium, Zinc and
	Calcium. Provides nutritional support
	during PMS, Oral Contraceptive use, and
	Menopause.*
	Protects Cells from Free Radicals with
	Antioxidant Vitamins A, C, and E.*

Bayer HealthCare LLC Consumer Care Division 36 Columbia Road P.O. Box 1910 Morristown, NJ 07962-1910

Phone: 973 254-5000

975 0162 LET 11596

5 th Panel of Carton	Promotes Bone Strength*
	Supports a Healthy Reproductive
	System*
Right Panel of Carton	Key ingredients for Women's Health*
	BONE STRENGTH: Calcium, Magnesium,
	Zinc, Vitamin D, Vitamin A
	• HEALTHY SKIN, HAIR & NAILS:
	Vitamin C, Vitamin B12, Iron, Zinc
	• SUPPORTS RESISTANCE: Vitamin A,
	Vitamin C, Vitamin E, Iron, Zinc
	• ENERGY: Vitamins B6, B12, Thiamin,
	Riboflavin, Niacin, Iron, Pantothenic Acid,
	Folic Acid
	• REPRODUCTIVE SYSTEM: Folic Acid,
	Vitamins B6, B12 & C, Calcium,
	Magnesium, Zinc
*These statements have not been evaluated by the Food and Drug	

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer HealthCare, Consumer Care Division has substantiation on file that the statements are truthful and not misleading. This notification is comprised of an original and two (2) copies.

Should you have any questions or need any additional information, please contact the undersigned at 973-254-4793 or Joanne Robinett at 973-408-8093.

Sincerely,

Catherine W. Fish

Associate Director, Regulatory Affairs

BAYER HEALTHCARE, CONSUMER CARE DIVISION